Site Amendment - Completing & Submitting

Site Amendments in REGIS

The following Site Amendment types can be submitted via REGIS;

❖ **Addition of a Site** update the study details of the additional site(s) and investigator(s). NSW sites will have a site application form generated in REGIS. *If Ethics is in REGIS, do not create this amendment.*

❖ **Change to CPI** notify the RGO of changes to the Coordinating Principal Investigator. *If Ethics is in REGIS, do not create this amendment.*

❖ **Change to PI** notify the RGO of changes to the Site Principal Investigator. *If Ethics is in REGIS, do not create this amendment.*

❖ **Request for an extension of HREC Approval** notify the RGO that the HREC has extended the project beyond the original period. *If Ethics is in REGIS, do not create this amendment.*

❖ **Changing Site Investigators and Administration Contact** notify the RGO of changes to the Site Investigators and add/remove Administration Contact (with 'Submit' access)

❖ **General Amendment** impacting on the type and frequency of services provided by supporting departments at participating sites.

❖ **Contract Changes** notify the RGO of changes to contract agreements.

For Ethics approved amendments within REGIS (NSW/ACT), amendments indicated above do not need to be created as the RGO will be notified of these amendments within REGIS.

If an ethics approved amendment has been **submitted from another Jurisdiction**, then the ethics documents are mandatory with the submission of the

governance amendment, where indicated in the form.

The following Site Amendments can be submitted to multiple sites at once: Change to CPI, Change to PI and Request for an extension of HREC Approval.

The following Site Amendments require individual submissions: Addition of a Site, General Amendment, Contract Changes and Changing Site Investigators and Administration Contacts.

The following Site amendments do not require Ethics approval: Changing Site Investigators and Administration Contacts.

How does it work in REGIS?
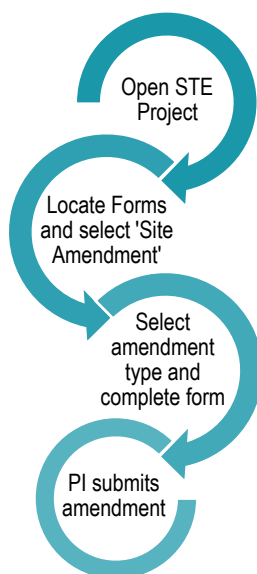
The PI or their delegate(s) can now submit the amendment. If you do not have access to submit, save the form and notify the PI it is ready for submission.

The PI can give view, edit and submit permissions to others.

Share with View Access: User can only view the application and/or forms, but not make changes.

Share with Edit Access: User can view the application and/or forms and make changes.

Share with Edit & Submit Access: User can view the application and/or forms, make changes, and submit on behalf of the CPI.

The amendment form can be saved and completed later. A saved amendment form is live for 365 days in REGIS.

Form Status

🔵 In Progress Form is initially with the applicant for completion and when the form has been reviewed and 'More Information Required' before a decision can be made.

🟢 Submitted Form is with the research office.

🟢 Approved Form has been reviewed and approved. An email notification will be sent to the PI, Admin Contacts and CPI, as appropriate.

Complete & submit the Site Amendment

Step 1. Locate STE project

If the project is not visible in the 'Top 5 projects' section, select Project at the top of the screen.
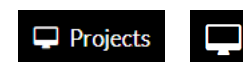
Click the required Project identifier (PID)

Step 2. Select the Site Project
Select the STE identifier and then select Forms.

Applications   Details   Forms   Milestones

Step 3. Open Amendment Form
Click '+New form' and select 'Site Amendment'

＋New form

Select the form you wish to fill out:

Reporting Local Safety Events to the Institution

Site Amendment

Step 4. Complete the amendment form
Choose the type of site amendment from the drop-down menu and complete the form.

Document Upload
REGIS has been designed to reduce the need for duplicate documents being submitted into the system where possible.

If **Ethics exists in REGIS** all Ethics approved documents (listed on the Ethics amendment approval letter) have been made visible to the Site/RGO.

If **Ethics exists outside of REGIS,** you will be guided to upload the Ethics approval email/letter AND the approved documents in a separate section "Ethics Approved Document Upload". It is recommended they are uploaded as a single .zip

Ethics Approved Document Upload
Upload the ethics approved document in this section. If there are **no documents required,** progress to the next section.
For a General Site Amendment, the 'Related Ethics Amendment Form ID' needs to be selected as it will allow the RGO to identify the HREC approved amendment and supporting documents.

Related Ethics Amendment Form

Form ID	Form Type
29977 ⌄	Notification of an amendment to a research study

Uploading a New Document: A new document is a document that does not yet physically exist in REGIS.

Note: If you are unsure if the document already exists in REGIS, select 'Yes' and if it does not appear under Document Title then change the response to 'No' and follow the below instructions.

Select +Add Another for a row to appear

＋ Add Another

Uploading **a new document** select 'No'

Upload as a new version *
○ Yes ● No

Document Title/Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Document Type: Select from the dropdown

This information will give the file a REGIS title.

Note: The Document Type and Description is what the Research Office will see and how the document will appear on the approval notification.

e.g. Participant Information Sheet Site PICF version 2 dated 13 January 2022

Document Type *	Document Descriptor *
Participant Information Sheet × ⌄	Site PICF version 2 dated 13 January 2022

Tip: Do not use any character or symbol in the document title that you cannot use in the electronic filename i.e. #%&{}<>? $!'+=`"|*

Upload attachment: Drag and drop or browse your local files for the new document.

Uploading a new version of a site approved document is used when the site document is already physically located in REGIS.

If you are uploading an **updated version of an approved** select yes.

Upload as a new version *
● Yes ○ No

Document Title/Descriptor: Select the form being updated from the dropdown options.

New Document Title: List exactly as you need the document to appear on the approval letter including the version and

date if it exists. Usually this corresponds with the footer of the document.

Document Descriptor *
Site PICF version 2 dated 13 January 2022

Document Filename: This will preload.

File Name	Size
✕ Site PICF v 2.docx	16.40 kB

Then drag and drop or browse your local files for the new document.

To add a tracked version of the document, select '+ Add another' and follow the 'Uploading a New Document' instructions.

Step 6. Declaration
The PI or delegate with 'Submit' access can submit the amendment. If you are not the PI or delegate, save the form and notify the PI or delegate once it is ready to submit.

Once submitted, the status of the form will be 'Submitted'. Each amendment form is given a unique identifier number.

� Title	� Status
029505 - Site Amendment	● Submitted

To download a copy of the site amendment and attachments, click the three dots next to the site amendment identifier and click 'Download Attachments'.

⋮ **⬇ Download Attachments**

What Next?
The amendment will be received by the Research Office managing the Site application. Depending on the type of amendment (HREC Extension, Change of CPI and Changing Site Investigators and Administration Contacts), no further action is required.

Once reviewed you will receive either an approval notification or a request for further information (see Governance Amendment – Responding to an Information Request).